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| 10/510,488 | 03/28/2005 | James Browning | MPA-003 | 1575 |

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| EXAMINER | |
|---|---|
| BURK, CATHERINE E | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/510,488 | BROWNING, JAMES | |
| | Examiner | Art Unit | |
| | CATHERINE E. BURK | 4185 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *28 March 2005, 20 June 2005, 24 March 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Specification*

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 32 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6960160 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other

because claim 32 is generic to all that is recited in claim 1 of U.S. Patent No. 6960160 B2.

3. In other words, claim 1 of U.S. Patent No. 6960160 B2 fully encompasses the subject matter of claim 32 and therefore anticipates claim 32. Since claim 32 is anticipated by claim 1 of the patent, claim 32 is not patentably distinct from patented claim 1. It has been held that the generic invention is anticipated by the species, see In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

### *Claim Rejections - 35 USC § 102*

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 14-16, 18, 24, 27, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovac (US 2001/0000533 A1).

5. Regarding claims **1-3, and 18**; Kovac discloses a system for the long term care of female incontinence comprising a rectangular mesh patch (34) (surgical implant) that includes at least two fixing zones, represented by the area surrounding holes (35-38) (pores) and a supporting zone passing under the endopelvic fascia (8) and indirectly under the urethra (4) (page 4, paragraph [0051] and fig. 7), formed by the remaining area of the patch (fig. 12). Anchor screws (27 and 28) (retaining means) are passed through holes (35 and 36) and are inserted into the posterior aspect of the pubic bone (page 5, paragraph [0061]) (view figs. 11 and 15).

6. Regarding claims **14-16**; Kovac discloses the surgical mesh implant is approximately 6 cm long and 3 cm wide.

7. Regarding claims **24 and 27**; Kovac also discloses a tool for inserting the patch comprising an elongate shaft (113) with a semi-blunt portion at the end of curved section (15) and a holding means in the form of bone anchor mount (107) for releasably mounting the surgical implant on the shaft (view figs. 14 and 15) via holes (35 and 36) (apertures) for implantation into the body (page 5, paragraph [0061]).

8. Regarding claim **32**; Kovac discloses a method for inserting a bone anchor engaged to a bone anchor implantation device comprising the steps of: creating an opening (incision) in the tissue between the vaginal wall and the urethra (claim 27) wherein the two bone anchors are implanted on each side of the urethra (claim 28) and locating a bone anchor implantation site on the posterior pubic bone (claim 22). The anchors are implanted into the pubic bone and therefore do no penetrate the rectus sheath.

### *Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovac (US 2001/0000533 A1) in view of Thompson (US 5997554 A).

11. Regarding claims **4 and 5**; Kovac does not disclose wherein the retaining means are moveable from an inserting position to a retaining position, nor does Kovac disclose wherein the retaining means comprises at least one projection which can project from the implant into the tissues of the retropubic space in at least one plane, the projection being moveable from a collapsed position to an extended position.

However, Thompson discloses a bone anchor that can move from a compressing (inserting) position, where the barbs are substantially straightened to permit insertion of the anchor into a bore created in bone, to a deployed (retaining) position, in which the barbs (projections) curvilinearly extend radially and axially away from the body of the anchor (in more than one plane) (col. 27, lines 45-55, and figs. 23-30).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Thompson.

Doing so would provide an anchoring mechanism that is less likely to detach from the bone after insertion than a conventional bone screw.

12. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovac (US 2001/0000533 A1) in view of Columbus (US 4444933 A).

13. Regarding claims **6 and 7**; Kovac does not disclose wherein the retaining means comprises cyanoacrylate glue.

However, Columbus discloses that cyanoacrylate adhesion compositions are recommended for medical and surgical use as an alternative to conventional sutures for repairing breaks or ruptures in bone (col. 1, lines 41-46).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Columbus.

Doing so would provide an alternative fixation method that would cause less morbidity at the surgical implant site.

14. Claims 8-11, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovac (US 2001/0000533 A1) in view of Fierro (WO 145589 A1).

15. Regarding claim **8**; Kovac discloses an embodiment of the invention comprising pointed first ends (fig. 13, elements 44 and 45) and base portions shown in figure 1 below (dotted arrows and letters were added by examiner for clarity) as imaginary lines between angles A and B, and angles C and D with longitudinal edges extending there between.

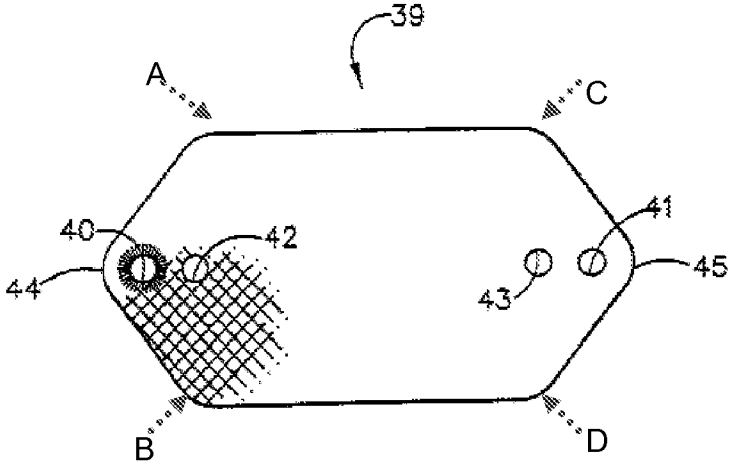


**Figure 1 Modified version of figure 13 from Kovac showing patch (39) and designating base ends of fixing zones.**

Kovac does not disclose wherein the longitudinal edges are notched to provide a row of projections extending outward from the longitudinal edges.

However, Fierro discloses a sling for treating urinary incontinence comprising a band (2) with middle part (3) containing a pad (6) (supporting zone) and two end parts (4) (fixing zones). In one embodiment, the end part (4) comprises a notched (projection) longitudinal edge extending between a pointed first end and a base (view fig. 8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Fierro.

Doing so would provide a method of joining two ends of the sling together without a suture.

16. Regarding claims **9 and 10**; Kovac does not disclose the implant comprises plastic material.

However, Fierro discloses the band may be made from any biocompatible, biological, or synthetic material that can be porous, microporous (absorbable), perforated, or impermeable depending on the properties sought. Examples include polypropylene or polyurethane (plastics) (page 6, lines 24-27).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Fierro.

Doing so would provide a device that can be adapted to reduce or eliminate friction between the sling and organs in contact with the sling.

17. Regarding claim **11**; Kovac does not disclose wherein the material of the supporting zone is more quickly absorbed by a body than material of the fixing zones.

However, Fierro discloses that it is possible for the pad (3) (supporting zone) to be made of a different material than the end parts (4) (fixing zones) and that the given list of materials on page 6, lines 24-27 would be suitable for either or both components. One can easily see that among all of the materials presented by Fierro, the supporting zone and fixing zone materials can be chosen such that the supporting zone will be more quickly absorbed by a body than the fixing zones.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Fierro.

Doing so would provide a device that remains fixed in place while the supporting zone erodes.

18. Regarding claims **19 and 20**; Kovac does not disclose wherein at least one of the fixing zones comprises pits that indent at least one surface of the fixing zone but do not extend through the fixing zone, nor does Kovac disclose wherein one of the fixing zones comprises slits that extend through the fixing zone.

However, Fierro discloses the end part (4) comprises a notched (projection) longitudinal edge extending between a pointed first end and a base (view fig. 8). The notched longitudinal edges form pits that do not extend through the entire fixing zone. Additionally, Fierro discloses holes (16) in the form of slits in an end part (4) of the invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Fierro.

Doing so would provide a method of joining two ends of the sling together without a suture.

19. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovac (US 2001/0000533 A1) in view of Tihon (US 6042536 A).

20. Regarding claims **12 and 13**; Kovac does not disclose a resilient zone interposed between the fixing and supporting zones that provides for resilient extension of the implant along its longitudinal axis.

However, Tihon disclose a bladder sling (1) with fixing zones shown as tabs on opposing ends of the sling (1) and a supporting zone shown as the area delineated by curved borders between fixing zones in fig. 3. Sling (1) comprises a flexible, stretchable sheath (10) that extends laterally across the support from the first fixing zone to the second fixing zone. Since this sheath extends across the longitudinal length of the sling, it is interposed between the fixing and supporting zones and also allows for resilient extension of the implant along its longitudinal axis.

It would have been obvious to one or ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Tihon.

Doing so would provide a device than can be stretched, to allow for insertion and movement within the body, and returned to its original size.

21. Claims 17 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovac (US 2001/0000533 A1) in view of Scetbon (US 6478727 B2).

22. Regarding claim **17**; Kovac does not disclose dimensions of thickness for the surgical mesh implant.

However, Scetbon discloses a sub-urethral tape for treating urinary stress incontinence having a thickness between 0.12 and 0.16 mm (120 to 160 μm).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Scetbon.

Doing so would provide a device that is of a thickness suited to the dimensions of retropubic space.

23. Regarding claim **23**; Kovac does not disclose a marker.

However, Scetbon discloses a central zone of the tape indicated by a colored marker (col. 6, lines 11-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Scetbon.

Doing so would provide a visual method for a user to optimally place the tape in order to avoid erosion or sclerosis of the urethra (col. 6, lines 10-11).

24. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovac (US 2001/0000533 A1) in view of Gellman (US 6042534 A) and Chehroudi (J Biomed Mater Res. 22(6): 459-73 June 1988).

25. Regarding claims **21 and 22**; Kovac does not disclose at least one microgroove provided on at least one fixing zone.

However, Gellman discloses a stabilization sling that can be made out of directionally oriented materials having filaments, grains, striations, or polymeric chains (fig. 7A-G). Those skilled in the art will appreciate that the grained materials may have ridges or grooves therein (col. 13, lines 12-27).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Gellman.

Doing so would provide a device with micro-surface properties that can be tailored to the needs of a specific case.

26. Kovac in view of Gellman does not disclose dimensions for width or depth of the microgrooves.

However, Chehroudi discloses epoxy resin structures have microgrooves measuring 10 μm deep and 17 μm across (page 460, Materials and Methods paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Gellman in further view of Chehroudi.

Doing so would provide a surface that is more biocompatible because it allows for migration and integration of surrounding cells.

27. Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovac (US 2001/0000533 A1) in view of Kammerer (US 2002/0077526 A1).

28. Regarding claims **28-30**; Kovac does not disclose wherein the holding means comprises a recess extending from the semi-blunt point capable of receiving a portion of the surgical implant.

However, Kammerer discloses a surgical instrument for inserting a sling beneath a urethra. The instrument comprises needle (10) with guide needle (110). Guide needle (110) includes an L-shaped groove (124) (recess). Sling mesh (12) is coupled to needle (10) which includes bore opening (120) and locking pin (122) which engages groove (124) and locks with a twist (page 4, paragraph [0048] and fig. 5C). When the needle (10) is twisted, the surgical mesh that is coupled to the needle (10) will also be twisted along its length. Due to the L shape of groove (124), a portion of guide needle (110) forming a wall is longer than a second portion of guide needle (110) forming an opposite wall (view fig. 5C).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Kammerer.

Doing so would provide a locking mechanism between the implant and insertion tool that would allow for greater maneuverability of the implant during insertion.

29. Regarding claim **31**; Kovac does not disclose an abutment located toward the first end of the elongate shaft capable of hindering movement of the surgical implant down the length of the shaft.

However, Kammerer discloses an embodiment of the invention that includes engaging groove (120) (figs. 7F and G) that is capable of hindering movement of the sling implant (12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the scope of Kovac in view of Kammerer.

Doing so would provide a device that is capable of holding the sling implant in place during insertion.

## *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention. Incontinence sling implants and implanting devices: Scetbon (US 20010018549) and Thompson (US 6042583 A).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE E. BURK whose telephone number is (571) 270-7130. The examiner can normally be reached on Monday-Thursday 8:30 AM - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CATHERINE E BURK/
Examiner, Art Unit 4185

/Terrell L Mckinnon/

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